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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,872	04/25/2001	Antonio J. Grillo-Lopez	P 0280609/2000-30-154A	4921

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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,872	GRILLO-LOPEZ, ANTONIO J.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-60 and 62-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-60 and 62-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Grillo-Lobez, A.

Date of priority: 04/25/2000

Request for Continued Examination

The request filed on April 13, 2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/840872 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 68-74 were newly added.

Claims 56-60, 62-74 are currently under consideration.

Rejections Maintained:

Claims 56-60, and 62-67 remain rejected and new claims 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,776,456 (Anderson *et al.*) in view of U.S. Patent No. 6,042,826 (Caligiuri *et al.*) and DeAngelis, LM (J.Neurooncol. Vol. 38 (2-3), 1998, pages 245-252) for the reasons of record. See Advisory Action mailed 10-20-2004 and the Action mailed 07-26-04.

With regards to new claims 67-74, it would have been further *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include radiolabeled and or drug/toxin conjugated antibodies because Anderson *et al.* teach (column 4, lines 17+) that the conjugation of a radioactive label or toxin improves the ability of the antibodies to be effective in the treatment of B-cell disorders. Such radiolabels include ^{131}I (column 4, line 22) and ^{90}Y

(column 9, line 20). The patent further teaches that ^{90}Y has several benefits including the longer half-life with no accompanying gamma irradiation in its decay.

Applicants reiterate (Response, page 5) that at the time of filing the instant application a skilled artisan would not have had a reasonable chance of success in practicing the claimed invention based on the unpredictability, in general, at treating a central nervous system (CNS) lymphoma. This argument has been considered but is not found persuasive in view of Caligiuri *et al.* (US Patent No. 6,042,826) which teaches methods for treating a primary central nervous system lymphoma in an individual comprising administering intrathecally or intralesionally compounds that are structurally related (i.e. antibodies) to the claimed administered compounds. Applicants further respond (page 6) that this conclusion constitutes the examiner's opinion only and is not supported by current evidence that treatment of CNS lymphomas and other CNS disorders remains highly unpredictable due to vulnerability of brain tissue to toxic leukoencephalopathy. This argument has been considered but is not found persuasive. On the contrary, patents are relevant as prior art for *all* they contain, and the Caligiuri *et al.* reference is enabling for the treatment of CNS lymphomas. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998). Applicants further appear to argue that the dangers associated with chemotherapy and intrathecal administration (i.e. Ruggiero *et al.*, Hara *et al.*, and Dettmeyer *et al.*, IDS) teach away from

successfully treating CNS lymphomas. This argument and the references have been carefully considered but are not found persuasive as the majority of current chemotherapeutic protocols employ compounds that can be highly toxic to cancer patients. Further, the Federal Circuit has reiterated that therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs marketed in the United States. See MPEP 2107.01

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Scott [v. Finney], 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 [(Fed.Cir. 1994)]. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

Claims 56-60, and 62-67 remain rejected and new claims 69-74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,776,456 (Anderson *et al.*) in view of the teachings of U.S. Patent No. 6,042,826 (Caligiuri *et al.*) and DeAngelis, LM (J.Neurooncol. Vol. 38 (2-3), 1998, pages 245-252) for the reasons of record and for the reasons set forth above. Applicants reiterate their arguments as set forth above. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER